SEP 2 0 2004 K042205 1/2

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Bone Fusion Plate System.

Submitted By:	Wright Medical Technology, Inc.
Date:	August 12, 2004
Contact Person:	Jeanine H. Redden
	Regulatory Affairs Specialist II
Proprietary Name:	Bone Fusion Plate System
Common Name:	Bone Fusion Plate
Classification Name and Reference:	21 CFR 888.3030 Plate, Fixation, Bone – Class II
Device Product Code and Panel Code:	Orthopedics/87/HRS

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Bone Fusion Plate System is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces.

Indications for Use:

- Fractures, osteotomies or arthrodesis of the first metatarsal-phalangeal joint
- Deformity due to hallus valgus
- Deformity due to arthritis in the first metatarsal-phalangeal joint
- Loss of motion- hallux rigidus
- Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint
- Revision procedures where other treatments or devices have failed; and
- Chronic instability in the first metatarsal-phalangeal joint

B. DEVICE DESCRIPTION

The Bone Fusion Plate System consists of plates, and screws. The design features of the components included in the Bone Fusion Plate System are summarized below:

Bone Fusions Plate
- Left and Right configurations
- Available in 2 options

2.7mm Cruciform Screws
- Non-locking
- Lengths available: 8, 10, 12, 14, 16, 18, 20, 22, 24mm

3.2mm Cruciform Screws
- Non-locking
- Lengths available: 14, 16, 18, 20, 22, 24mm

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indication for use of the Bone Fusion Plate System is substantially equivalent to the predicate device HALLU® Plate System. The safety and effectiveness of the Bone Fusion Plate System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2004

Ms. Jeanine H. Redden
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K042205
Trade/Device Name: Bone Fusion Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: August 12, 2004
Received: August 16, 2004

Dear Ms. Redden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Bone Fusion Plate

Indications For Use:

The Bone Fusion Plate System is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces.

Indications for Use:

- Fractures, osteotomies or arthrodesis of the first metatarsal-phalangeal joint
- Deformity due to hallus valgus
- Deformity due to arthritis in the first metatarsal-phalangeal joint
- Loss of motion- hallux rigidus
- Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint
- Revision procedures where other treatments or devices have failed; and
- Chronic instability in the first metatarsal-phalangeal joint

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042205